

**REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

**I. CLAIM STATUS & AMENDMENTS**

Claims 1-22 were pending in this application when last examined.

Claims 1-5, 11 and 13-18 were rejected.

Claims 6-10, 12 and 19-22 were withdrawn as non-elected subject matter.

Claims 1, 4, 5, 11, 13-15 and 17 have been amended.

Support for the phrase "95% homology" added to claims 1 and 13 can be found in the specification, for example, at page 4, lines 8-13.

Support for the stringent conditions added to claims 1 and 13 can be found in the specification, for example, at page 4, lines 18-24.

Support for the underlining of the name of the microorganism in claims 4 and 17 can be found in the original claims.

Support for the term "isolated" added to the claims can be found in the specification, for example, at page 2, lines 16-18 and page 12, line 28 to page 13, line 1 (Example 2).

Support for the amendments to claim 13 to better clarify the members of the Markush group for the nucleotide sequences of the promoter and the terminator can be found in the specification, for example, at page 5, lines 5-32.

Therefore, no new matter has been added by this amendment.

Claims 2-3 have been canceled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any canceled subject matter.

Claims 1 and 4-22 are now pending in this application.

## **II. REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION**

Claims 1-5, 11, 13 and 15-18 were rejected under 35 U.S.C. § 112, first paragraph, on the basis that the specification lacks written description support for the claimed invention. See pages 2-6 of the Office Action.

It is respectfully submitted that the present amendment overcomes this rejection.

Specifically, “modified nucleotide sequence” and the “one or more modifications” language has been deleted from the claims.

In addition, claims 1 and 13 have been amended to replace “70% homology” with “95% homology” as described in the specification at page 4, lines 8-10. The specification provides sufficient relevant identifying characteristics, both structural and chemical, such that one skilled in the art would reasonably believe that Applicants had possession at the time of filing of a sequence or a fragment thereof having at least 95% homology to SEQ ID NO: 1.

The test for sufficiency of written description is whether the disclosure of the application reasonably conveys to the artisan that the inventor had possession at the time of filing of the subject matter which is claimed. See M.P.E.P. § 2163, I, 2100-159, 1<sup>st</sup> column, 2<sup>nd</sup> paragraph.

This requirement may be satisfied by: (1) a reduction to practice; (2) a reduction to drawings/chemical formulas; (3) a disclosure of relevant identifying characteristics, such as structure or other physical and/or chemical properties, to sufficiently describe the claimed invention in full, clear, concise and exact terms; (4) a disclosure of functional characteristics coupled with a known or disclosed correlation between function and structure sufficient; (5) a sufficient description of a representative number of species; or (6) a combination of the above, sufficient to show Applicants were in possession of the invention. See M.P.E.P. § 2163, 2100-170 to 2100-174, II, A, 3 a(i)-(ii).

In the instant case, the specification contains a detailed description of the nucleotide sequence of SEQ ID NO: 1 and how to construct and isolate this sequence. See page 3, lines 29-32 (Figures 1-2), page 5, lines 20-36, page 9, line 17 to page 13, line 25 (Examples 1-4) of the specification. Also, the specification, at page 4, lines 25-32 describes the minimum length of a fragment having the requisite promoter or terminator activity. The specific sequence set forth in SEQ ID NO: 1 and

the construction and restriction maps in Figures 1-2 provide the requisite relevant identifying structural and chemical characteristics for this sequence.

Also, on page 4, the specification discloses procedures for identifying a sequence that hybridizes under stringent conditions to SEQ ID NO: 1. On pages 13-14 (Examples 3-4), the specification also contains a detailed description of using techniques for expressing a protein encoded by the sequence that hybridizes under stringent conditions, and then testing for the requisite biological activity. Such techniques are common and routine in the art.

Based on this disclosure and the general knowledge in the art, the skilled artisan would be able to isolate a sequence that hybridizes under stringent conditions to SEQ ID NO: 1, test the protein encoded by this sequence for the requisite biological activity, and then sequence the nucleotide to determine the requisite percent homology. As such, the specification satisfies the requirement for providing sufficient relevant identifying characteristics both structural and chemical (SEQ ID NO: 1 and the requisite biological activity) to sufficiently describe the claimed invention in clear, concise and exact terms. Also, such a disclosure satisfies the requirement for a description of functional characteristics coupled with a known or disclosed correlation between structure (SEQ ID NO: 1 and 95% homology thereto) and function (the requisite biological activity).

Therefore, one skilled in the art would reasonably believe that Applicants were in possession of the claimed invention at the time of filing.

In view of the above, the rejection of claims 1-5, 11, 13 and 15-18 under 35 U.S.C. § 112, first paragraph, is untenable and should be withdrawn.

### **III. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH**

Claims 1-5, 11 and 13-18 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite for the reasons set forth on pages 6-7 of the Office Action.

It is respectfully submitted that the present amendment overcomes this rejection.

Specifically, the phrases “a modified nucleotide sequence” and “one or more modifications selected from a substitution, a deletion, an addition, and an insertion” have been deleted from the claims, thereby obviating this rejection.

In view of the above, the rejection of claims 1-5, 11 and 13-18 under 35 U.S.C. § 112, second paragraph, is untenable and should be withdrawn.

#### **IV. REJECTION UNDER 35 U.S.C. § 101**

Claims 1-5, 11, 13 and 15 were rejected under 35 U.S.C. § 101 as drawn to non-statutory subject matter. See page 8 of the Office Action.

It is respectfully submitted that the present amendment overcomes this rejection. Specifically, the claims have been amended to recite "an isolated promoter" or "an isolated expression vector" as suggested by the Examiner, thereby obviating this rejection.

Thus, the rejection of claims 1-5, 11, 13 and 15 under 35 U.S.C. § 101 is untenable and should be withdrawn.

#### **CONCLUSION**

In view of the foregoing amendments and remarks, the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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